Testimony of

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Before the

HOUSE JUDICIARY SUBCOMMITTEE ON IMMIGRATION, BORDER SECURITY AND CLAIMS

Oversight Hearing on

"The Energy Employees Occupational Illness Compensation Program Act—Are We Fulfilling the Promise We Made to these Veterans of the Cold War When We Created the Program?"

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2142 Rayburn House Office Building

Chairman Hostettler, Ranking Member Jackson-Lee, and Members of the Subcommittee, thank you for the opportunity to appear before you today to more fully address certain issues regarding my firm, S. Cohen & Associates (SC&A, Inc.), that were raised before the Subcommittee at previous hearings. We will also present to the Subcommittee SC&A's perspectives regarding some of the issues that have emerged during our support of the Advisory Board on Radiation and Worker Health (the Advisory Board) on matters related to the review of Special Exposure Cohort Petitions and NIOSH's evaluation of those petitions under the Energy Employees Occupational Illness Compensation Program Act (the Act or EEOICPA).

SC&A previously submitted a statement to the Subcommittee at the hearings held here on March 1, 2006. In that statement, we provided an overview of who we are, our role in support of the Advisory Board, and how we approached our technical work. We also provided descriptions of our contractual requirements and our accomplishments up until that date. This information is not repeated here, except to reintroduce who we are and update some of the previously filed information to the extent that it is pertinent to the subject of this hearing.

SC&A is a small business providing professional services in the radiation sciences. The majority of our work over the past 25 years has been for government clients, including the Environmental Protection Agency, Nuclear Regulatory Commission, Centers for Disease Control and Prevention, and the Defense Nuclear Facilities Safety Board. Under a contract with the National Institute of Occupational Safety and Health (NIOSH), SC&A has been the technical support contractor to the Advisory Board since October 14, 2003. SC&A's role under this contract is to provide technical assistance to the Board in fulfilling its mandate under EEOICPA, which has

amongst its charges the task of reviewing a reasonable sample of dose reconstructions for scientific validity and quality, assessing the methods and procedures for dose reconstruction, reviewing Special Exposure Cohort (SEC) petitions, and advising the Secretary of Health and Human Services (HHS) in these matters. I am the SC&A project manager. I have a PhD in health physics, am certified by the American Board of Health Physics, and have over 30 years professional experience in the field of radiation protection.

My statement today is divided into two parts. The first part presents SC&A's perspectives regarding emerging technical issues pertaining to the review of SEC petitions and NIOSH's evaluation reports of SEC petitions. The second part presents SC&A responses to issues raised at previous hearings pertaining to SC&A's role in support of the Advisory Board and allegations regarding any possible SC&A conflicts of interest.

Emerging Technical Issues Pertaining to SEC Petitions

At the March 1, 2006 hearing, SC&A described the following scope of services for the Advisory Board with respect to SEC petition reviews that were authorized at that time: (1) prepare a report that presents a review of the procedures developed by NIOSH for use in evaluating SEC petitions, (2) prepare procedures to be used by SC&A and the Advisory Board for reviewing SEC petitions and/or SEC evaluations prepared by NIOSH, (3) review the Ames Laboratory SEC petition, and (4) perform focused reviews of Board-selected issues related to the Y-12 and Rocky Flats SEC petitions. We were also directed to provide technical support to the Board on the Mallinckrodt and Iowa Army Ammunition Plant SEC petitions by evaluating the relevance of certain issues raised in the site-profile review process to determining the feasibility of dose reconstruction under the SEC regulation (42 CFR Part 83).

With the exception of our review of the Rocky Flats SEC petition and NIOSH's evaluation of that petition, the above-described SEC-related services have been completed. In addition, since that time, SC&A was directed by the Advisory Board to perform additional SEC-related investigations. The additional services include a review of the Chapman Valve SEC petition and NIOSH's evaluation of that petition, and the so-called "250 work-day investigations." The scope of work regarding the former is self-explanatory, but the latter requires some explanation. The 250 work-day investigation specifically addresses technical issues related to whether the Special Exposure Cohort status that was granted to the Nevada Test Site, Pacific Proving Grounds, and Iowa Laboratory petitioners should be expanded to include members of the cohort who worked at these facilities for less than 250 days. These investigations are currently underway.

We have been requested by the Subcommittee to address "emerging SEC-related issues" that have surfaced in the conduct of the SEC-related work we have performed to date. The following briefly responds to this request. These issues have emerged during the performance of our SEC-related investigations, and we believe that they have broader applicability to the review of SEC petitions in general.

1. Issue No. 1: Boundaries on the "maximizing" approach for determining whether radiation doses can be estimated with sufficient accuracy

Part 83.13 (c)(1) of Title 42 of the Code of Federal Regulations states that:

> *Radiation doses can be estimated with sufficient accuracy if NIOSH has established that it has access to sufficient information to estimate the maximum radiation dose, for every type of cancer for which radiation doses are reconstructed, that could have been incurred in plausible circumstances by any member of the class, or if NIOSH has established that it has access to sufficient information to estimate the radiation doses of members of the class more precisely than an estimate of the maximum radiation dose [42CFR83.13(c)(1)] .*

In support of the Advisory Board with respect to the Iowa Army Ammunition Plant (IAAP) SEC petition, SC&A found that a large portion of the data required to evaluate whether doses could be reconstructed with "sufficient accuracy" involved the review of classified data pertaining to the radiation fields in the vicinity of nuclear weapon warheads. Because of the classified nature of some of the data required to reconstruct the doses to some members of the cohort, NIOSH developed a dose reconstruction strategy for the early period of IAAP operation up to and including 1962, that employed highly conservative "upper bound" estimates that were, in the main, not based on measurements but on a hypothetical "generic pit." This "generic pit" did not correspond to any real device, but was a paper artifact constructed to ensure that the estimated doses would be higher than those actually experienced by workers. However, our investigations revealed that the use of this "work around" for dealing with classified data led to the introduction of upper-bound estimates that were about ten times higher than those estimated for workers who did the same or similar type of work at the same facility during or after 1963, when the restriction on classification of data no longer applied. This appeared to be arbitrary and inequitable to the later workers, since there was a real possibility that they would be denied compensation for the same type of work for which the earlier period workers, up to 1962, would receive compensation. This situation arose purely from the approach adopted to protect classified data and was not related to working conditions. Furthermore, since there were no radon data for the IAAP for the structures in which nuclear weapons were assembled, radon data from Pantex, situated at a low radon area, were applied. SC&A questioned whether such strategies to reconstruct doses met the intent of the criteria of "sufficient accuracy" and whether it was appropriate to apply such bounding approaches to some workers but not to others who might have performed similar job functions. At what point does advancing maximizing assumptions stretch technical plausibility to levels that are inappropriate?

The generic SEC-related issue that emerged from these investigations can be stated as follows:

> ***The use of maximizing assumptions for classified information should be consistent with maximizing assumptions used for other workers.***

2. Issue No. 2: Constraints placed on the independent technical review of an SEC petition due to the classified nature of some of the records required for dose reconstruction

SC&A was directed by the Advisory Board to review the IAAP SEC on an accelerated schedule with much of the scope of the review pre-established. Such expedited reviews were certainly within the scope of SC&A services. However, they do have certain drawbacks that need to be appreciated. Specifically, SC&A was not provided the opportunity to conduct an independent records' review and retrieval, particularly for the available classified information. Instead, NIOSH arranged a DOE briefing with NIOSH-collected documents present for restricted onsite review. All notes taken had to be submitted for DOE classification review and clearance before they could be used in SC&A's report to the Board. In the meantime, no communication was permitted between the cleared members of SC&A team for IAAP and non-cleared members, necessitating two separate reports. Some of these restrictions are recognized as necessary for national security, but they could result in reviews that are not as thorough as might be needed to support decision-making.

The generic SEC-related issue that emerged from these investigations can be stated as follows:

Is there a procedure that could be developed to better allow integration of classified information?

3. Issue No. 3: Access to data and records

SC&A's evaluation of the "completeness" and "adequacy" of a site's radiation dose records to validate NIOSH's basis for denial rests substantially on SC&A's ability to access those records upon which NIOSH is basing its conclusion, and to cross-compare petitioners' allegations of exposure with this record. Even if full access is granted, SC&A believes that there are some technical issues that require SC&A to access original DOE records that are not necessarily part of the NIOSH database. Under new policies recently implemented by NIOSH to protect Privacy Act records, constraints have been placed on SC&A's access to claimant records. Since this is a recent policy change, it is difficult to judge at this time the magnitude of the impacts the new policy will have on our ability to complete our investigations in a timely manner. However, to date, the new access restrictions have hampered SC&A's work on the Rocky Flats SEC petition and its investigation of the issues relating to the addition of Nevada Test Site workers with less than 250 days of employment in the 1951–1962 period to the Special Exposure Cohort. It has also hampered other non-SEC-related work. As of today, we understand that NIIOSH is re-evaluating this data access issue.

The generic SEC-related issue that emerged from these investigations can be stated as follows:

In order to fulfill its contractual obligations to the Advisory Board, SC&A must have unfettered access to not only NIOSH's database upon which dose reconstructions are based, but also access to DOE records that may not be part of NIOSH's database. Of course, where classified data are concerned, SC&A assigns personnel with the appropriate level of clearances to access those

documents, and all material must be managed under approved Privacy Act controls, as applicable.

4. Issue No. 4: Data integrity issue resolution

A major issue raised by Rocky Flats SEC petitioners is the reliability of the database upon which dose reconstructions are based, including the possibility of fraudulent record keeping and the deliberate destruction of records. We refer to this as the "data integrity issue." Decisions regarding a given SEC petition cannot be made until a determination can be made regarding the integrity of the data. At present, no guidance exists regarding the process by which data integrity can be judged, nor the criteria to be used when sufficient evidence exists that data integrity issues may be so pervasive as to prevent the Board from making a determination that doses can be reconstructed with "sufficient accuracy." A conclusion of systemic problems with the records (as opposed to isolated, individual ones) is only likely with a "smoking gun" memo, record, or other incontrovertible piece of evidence. There is also a complementary issue of data completeness. There are sometimes gaps in dose records and in databases of varying degrees. The significance of these gaps varies, depending on their extent and the nature of the complementary data available to fill the gaps. This issue is linked to the question of whether available records are adequate for dose reconstruction. For instance, the investigation of the external dose data completeness and adequacy at Y-12 was lengthy because NIOSH asserted that the monitored employees were the ones at highest risk of exposure, while the SC&A analysis indicated that that was sometimes not the case in some time periods relevant to the SEC.

Under these circumstances, the workers collectively can file affidavits and show considerable circumstantial evidence regarding data integrity and completeness issues, but be ultimately denied compensation because there may be hypothetical explanations that can be used to dismiss the allegations. There may exist analytical methods and decision criteria that can be developed to help make data integrity and completeness judgments, but they have not yet been developed.

The generic SEC-related issue that emerged from these investigations can be stated as follows:

While the "integrity" of dose data is a fundamental basis for judging an SEC, there is no guidance or threshold criteria for judging how documented instances of fraud or error rise to an overall systemic concern. Further, the petitioners have no or limited access to the NIOSH and DOE records that would enable them to develop evidence of a systemic problem. Further confounding the ability to judge data integrity are limitations on the ability of the Board and its contractors to gain timely access to NIOSH and DOE records, including claimant records that have and have not been adjudicated. The issue of data completeness and adequacy as well as verification of databases has also emerged as a significant one. In the absence of agreed criteria for determining data integrity, adequacy and completeness, the investigation of these issues can become rather prolonged.

Responses to Issues Raised Regarding SC&A at Previous Subcommittee Hearings

During the March 1, 2006 hearing, Mr. Shelby Hallmark, Director, Office of Workers Compensation Programs, U.S. Department of Labor, responded to post-hearing questions from the Honorable John N. Hostettler. Chairman Hostettler asked the following question, "What is the definition of "balance" as referred to in the OMB document in your opinion? Do you think there is a problem with the audit contractor employees because of conflicts of interest or bias? If so, how do you see that as negatively affecting the claims process?"

Mr. Hallmark responded as follows:

> *It would not be appropriate to comment on internal deliberations involved in the development of the President's budget. However, as I testified on March 1, 2006, in my view, the process whereby the SC&A contract staff have critiqued NIOSH's dose reconstruction, site profiles, and SEC petition evaluations appears to have exceeded the statutory mandate to the Board, which is to evaluate the scientific validity and accuracy of NIOSH's work. SC&A representations before the Board have instead focused almost exclusively on whether or not the assumptions utilized by NIOSH in a given context could have been even more "claimant favorable" – that is, whether there might be assumptions or statistical techniques that would even further overestimate the dose to which a worker or group or workers were exposed. This has meant that the contractor (and subsequently the Board) has spent little time focusing on whether NIOSH's assumptions are plausible, realistic, valid, and sufficiently accurate for compensation determinations, and almost all their time considering whether there might be some possibility that the exposure could have been even greater that estimated.*
>
> *The issue of the contractor's potential conflict of interest was also addressed in my testimony on March 1. Since that time, SC&A's specific conflict of interest with respect to the Pacific Proving Ground and the Nevada Test Site has been noted by the Advisory Board, and I believe SC&A has been recused from involvement at those sites. I understand that individual employees of SC&A may also have potential conflicts at various sites, either due to former employment with DOE or the U.S. Government. Individuals who are currently employed as advisors to plaintiffs in such suits would have a vested interest in magnifying exposures and the potential for health endangerment at those sites. Such conflicts of interest need not distort the findings of the program if they are fully reported with respect to previous work for DOE or DOE contractors and employment with plaintiff groups, if appropriate recusal actions are taken, and if the Board and the support contractor apply the statutory criteria ("scientifically valid and accurate") in evaluating NIOSH's activities.*

This statement and several other statements made by Mr. Hallmark at the March 1, 2006 hearing raise questions regarding SC&A's ability to provide unbiased technical support to the Advisory Board. SC&A would like to take this opportunity to rebut these statements.

I would like to begin by repeating some of the material I provided in my March 1, 2006 statement that has applicability here, as follows.

All tasks under this contract are performed in accordance with Federal acquisition regulations and protocols mandated by the Federal Advisory Committee Act (FACA). In summary, the Board, in open session, identifies tasks that they would like SC&A to perform, and that are within SC&A's contractual statement of work. The NIOSH Designated Federal Official, who currently also serves as the NIOSH Project Officer for this contract, and the NIOSH Contracting Officer participate in this process. Once the Board agrees on the scope of a given task order, the Board, in cooperation with the NIOSH Project Officer and Contracting Officer, issues a Task Order Request for Proposal (TORP). In response to the TORP, SC&A prepares a proposal of work, which includes the task order scope of work, a budget, schedule, technical approach, and assigned personnel. The Board and the NIOSH Contracting Officer review SC&A's proposal, provide any comments or additional direction to SC&A, and SC&A submits a revised proposal, as required. During open session, the Board approves the proposal of work and work begins.

Before work on a task order can begin, SC&A is required to submit a quality assurance plan and a conflict of interest plan to implement controls over documents as needed in order to meet the requirements of the Privacy Act, and to prepare written technical procedures that must be reviewed and approved by the Board in open session. The procedures that SC&A has prepared to date flow directly from the Act and the regulations that implement the Act, namely 42 CFR Part 82, which deals with dose reconstructions, and 42 CFR Part 83, which deals with SEC petitions. Hence, everything we do is designed to assess the degree to which NIOSH work products under the Act meet the letter and intent of the Act and its implementing regulations. I would like to refer the Committee to a statement placed on the record by Dr. Sanford Cohen, President and CEO of SC&A, Inc. at the March 1, 2006 meeting. In that statement, Dr. Cohen testified that, " SC&A has never performed work on behalf of workers claiming benefits under the EEOICPA." However, Mr. Hallmark's statements might pertain to work SC&A performed under contract to the People of the Republic of the Marshall Islands, where SC&A, including Dr. Hans Behling and I, provided testimony on behalf of the people of the northern atolls of the Marshall Islands seeking compensation from the government of the Republic of the Marshall Islands. This work does not constitute a conflict of interest under our contract with NIOSH or under our conflict of interest plan.

Our conflict of interest plan, which has been approved by NIOSH and the Advisory Board has only two "bright lines." The first is that no individual who has ever defended the Government against a claim can work on this project. The second is that neither SC&A nor any of its subcontractors can work on this project at the same time that they are under contract with NIOSH or any of its subcontractors on the EEOICPA program. We are also required to disclose work that any of our personnel or contractors ever performed for DOE. Individuals that have worked at a given DOE site cannot serve as the lead investigator for investigations pertaining to

that site. SC&A maintains a web site where everyone working on this project is required to provide a signed disclosure statement.

In addition, SC&A has recently installed a "firewall" to prevent conflicts of interest between this work that we are performing for NIOSH and other dose reconstruction work that the firm is performing for DTRA. The provisions of our conflict of interest plan are rigorously maintained by our conflict of interest project officer, Dr. Steven Ostrow. Dr. Ostrow diligently ensures that all personnel adhere to the conflict of interest plan by training new personnel on the implementation of the plan and verifying that monthly billings are in accord with the plan. If Mr. Hallmark is aware of any deviations from these requirements, we will take this very seriously and take corrective actions as necessary.

By the nature of his statements, we believe that Mr. Hallmark may be concerned with the fact that Dr. Makhijani has in the past provided expert testimony for workers (in one lawsuit in the 1990s) or for neighbors of some nuclear weapons' facilities. Such activities do not constitute a conflict of interest under the terms of our conflict of interest plan which explicitly follow the requirements set forth in the original NIOSH solicitation and which has been approved by NIOSH and the Advisory Board.

SC&A has conflict of interest criteria defined by its contract that were put in place by NIOSH and the Board. Serving as an expert witness on behalf of plaintiffs against the DOE is not part of the conflict of interest criteria set by the Board. Moreover, SC&A goes beyond formal conflict of interest requirements that we must fulfill in assuring the scientific validity and objectivity of our reports. We have senior staff members and associates who are exceptionally well qualified and are among the world leaders in their fields. Their backgrounds are varied and range from work in the nuclear industry to work in the public interest sector to contracting with government. Many serve or have served in expert capacities on advisory committees and on bodies such as the International Commission on Radiological Protection and the International Atomic Energy Agency. SC&A's review procedures ensure that findings are reviewed independently of the authors of the report. I have complete confidence in the scientific integrity of our process. As for SC&A team members having served as plaintiff experts, SC&A is aware of this. We are also aware of work in industry or the Department of Energy by other team members. It is a strength of our team in that its members are all committed to scientific integrity of our work and come from varying backgrounds and experience.

Finally, Mr. Hallmark believes that SC&A's audit findings consistently find that NIOSH's dose reconstructions underestimate doses. Mr. Hallmark is not correct in this belief. As part of our audit services, SC&A maintains a relational database that allows the user to prepare summary statistics that characterize the various SC&A audit report findings. One such audit report was prepared on February 28, 2006. (This report can certainly be updated if so requested by the Board.) At that time, SC&A had completed the audits and issue resolution discussions with NIOSH for 60 dose reconstruction cases selected by the Advisory Board. We evaluated these 60 case reviews to assess whether the associated findings were considered by SC&A to have resulted in (1) an underestimate of the NIOSH-derived dose, (2) an overestimate of the NIOSH-derived dose, or (3) no consequential effect on the dose. The results of this evaluation are summarized in the following table.

	Number of Findings			Total Findings
	Underestimated Dose	Overestimated Dose	No Effect on Dose	
1st Set of 20 Cases	40	21	10	71
2nd Set of 18 Cases	29	36	48	113
3rd Set of 22 Cases	33	27	5	65
Total	102 (41%)	84 (34%)	63 (25%)	249

Note that as of February 28, 2006, we completed our audits of 60 cases and believe that the distribution of the findings is relatively balanced and what might be expected for this type of review.